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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,439	10/25/2001	Bill H. McAnalley	013258.0294	2421

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EXAMINER
COE, SUSAN D

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,439	MCANALLEY, BILL H.	
	Examiner	Art Unit	
	Susan Coe	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Claims 1-27 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 18 and 19 are indefinite because it is unclear what saccharides are considered "essential saccharides."

3. Claim 20 is indefinite because it is unclear what physical effects are included in "bioregulation of trauma stress."

4. Claim 24 is indefinite because it is unclear what activities are considered to be encompassed by "toxin-related activities."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 5-7, 20, 22, and 24-27 rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,241,983.

Applicant's claims are drawn to a composition that contains beta-glucan with citrus pectin and / or lactoferrin.

US '983 teaches a composition that contains beta-glucan, pectin, and lactoferrin (see claims 2 and 21). The pectin can be citrus pectin (see column 8, line 5).

US '983 does not teach that their composition has all of the effects on the body claimed by applicant. However, since the composition of US '983 is the same as applicant's composition, the composition of US '983 would inherently have to have the same effects on the body if applicant's composition functions as claimed.

6. Claims 7 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 5,024,996.

Applicant's claims are drawn to a composition of beta-glucan and pectin.

US '996 teaches a composition that contains beta-glucan and pectin (see claim 21). US '996 does not specifically teach that the pectin is citrus pectin; however, pectin is the same

despite the source of the pectin. Therefore, the use of citrus pectin is not considered to make the claims patentable over US '996.

US '996 also does not specifically teach that their composition has all of the effects on the body claimed by applicant. However, since the composition of US '996 is the same as applicant's composition, the composition of US '996 would inherently have to have the same effects on the body if applicant's composition functions as claimed.

7. Claims 7 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No. 3,947,604.

US '604 teaches a composition that contains beta-glucan and pectin (see claims 1 and 4). US '604 does not specifically teach that the pectin is citrus pectin; however, pectin is the same despite the source of the pectin. Therefore, the use of citrus pectin is not considered to make the claims patentable over US '604.

US '604 also does not specifically teach that their composition has all of the effects on the body claimed by applicant. However, since the composition of US '604 is the same as applicant's composition, the composition of US '604 would inherently have to have the same effects on the body if applicant's composition functions as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4 and 8-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,576,015, US Pat. No. 5,531,989, and WO 97/05884.

The claims are drawn to a composition that comprises beta-glucan, lactoferrin, colostrum, saccharides and pectin.

US '015 teaches that beta-glucan strengthens the immune system (see column 1, lines 20-38).

US '989 teaches that a composition containing pectin, lactoferrin, and saccharides strengthen the immune system (see column 3, lines 47-50 and column 4, lines 1-20). The pectin can be from citrus (see column 7, lines 13-14).

US '884 teaches that lactoferrin and colostrum strengthen the immune system (see page 3, second paragraph).

These references show that it was well known in the art at the time of the invention to use beta-glucan, colostrum, lactoferrin, saccharides and pectin in compositions that strengthen the immune system. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in immune strengthening compositions, an artisan of ordinary skill would have a reasonable expectation that

a combination of the substances would also be useful in creating immune strengthening compositions. Therefore, the artisan would have been motivated to combine beta-glucan, colostrum, lactoferrin, saccharides and pectin into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references do not teach using saccharides from all of the sources claimed by applicant in claim 19. However, these are all known sources of saccharides. Therefore, it is considered an obvious modification of what is taught in the references to use saccharides from the sources claimed by applicant.

The references also do not specifically teach administering the composition in the chewable delivery system claimed by applicant. This form of administration is well known in the art to be an acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the references in the claimed form would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the references in the form claimed by applicant.

The references also do not specifically teach adding citric acid, dextrose, magnesium stearate, silicon dioxide, and stearic acid to the composition. However, these ingredients are well known in the art to be added to pharmaceutical substances as part of a carrier system. Therefore, it is considered obvious to add these ingredients to the pharmaceutical composition taught by the references.

In addition, the references also do not specifically teach adding the ingredients in the amounts claimed. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
May 21, 2002

LEON B. LANKFORD, JR.
PRIMARY EXAMINER